REMARKS

Claims 9, 10, 18, 19, and 22-33 are pending. Claims 11-17, and 20-21 were canceled as being drawn to a non-elected invention.

The Examiner acknowledges that claim 10 would be allowable if amended to put it into independent form; accordingly , the appropriate amendment was made to put this claim into condition for allowance.

New claims 22-33 were added. The amendment to claims 18-19 and new claims 22-33 are supported by disclosure at page 6, line 24, to page 7, line 14, of the specification. The amendment to claim 19 is supported on at page 2, lines 22-23, and at page 21, line 21, of the specification.

The specification was amended to insert the proper serial number of the utility patent application from which the present divisional application claims priority.

No new matter has been added by this amendment.

35 U.S.C. § 102

Claim 18 was rejected for anticipation by Docherty or WO9406919. The claim has been amended to require at least 10 residues of SEQ ID NO:4. Since the sequence alignments revealed a 7-residue overlap with Docherty and an 8-residue overlap with WO9406919, the claim as presently amended is not anticipated by either of the cited reference.

35 U.S.C. § 112, second paragraph

Claim 19 was rejected for indefiniteness. The claim was amended as suggested by the Examiner to recite the ATCC designation number for the Mab 3B2-producing hybridoma cell line. Applicant therefore requests withdrawal of this rejection.

35 U.S.C. § 112, first paragraph

Claims 9 and 18-19 were rejected under § 112 for overbreadth and lack of written description.

Enablement/Overbreadth

On page 9, lines 6-13, of the Office Action, the Examiner stated:

> Claims 9 and 18-19 are rejected under 35 U.S.C 112, first paragraph, because the specification, while enabling for the polypeptide of SEQ ID NO:4 encoded by the DNA of SEQ ID NO:3 for generating antibodies for activated platelets and for thrombus; does not reasonably provide enablement for any substantially pure polypeptide comprising a sequence identical to at least 95% of SEQ ID NO:4 in claim 9; any polypeptide comprising any antigenic fragment of the polypeptide in claim 18; or any substantially pure polypeptide having the sequence of a naturally-occurring platelet activation polypeptide that comprises any epitope which binds to Mab 3B2 in claim 19. (emphasis in original)

Claim 9 has been amended to delete the reference to per cent identity; claim 9 now requires that the claimed polypeptide contain the amino acid sequence of SEQ ID NO:4. Therefore, the rejection of claim 9 should be withdrawn.

Claim 18 requires an antigenic fragment of SEQ ID NO:4 that is at least 10 amino acids in length and lacks a transmembrane domain of the defined sequence. Armed with the amino acid sequence of the full-length naturally-occurring APP-2 protein (SEQ ID NO:4), it is well within the skill of an average molecular biologist to make polypeptides which are shorter in length than the full-length protein and have the structural requirements defined by the amended claim. As was stated in the specification of the application (e.g. at page 6, lines 29-31), such methods (e.g., chemical synthesis, expression of recombinant nucleic acid fragments, or enzymatic digestion) were well known in the art at the time the application was filed. Applicants therefore submit that amended claim 18 is fully enabled by the specification as filed.

Claim 19 has been amended to require a polypeptide that binds to Mab 3B2 and contains fragment of the sequence defined by SEQ ID NO:4. It is well established in patent law that a requirement of some experimentation by a skilled person does not preclude enablement; all that is required is that the amount of experimentation not be *unduly extensive*. The courts have stated that "The test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed." *In re Wands*, 858 F.2d at 737, 8 USPQ2d at 1404 (*citing, In re Angstadt*, 537 F.2d 489, 502-04, 190 USPQ 214, 218 (CCPA 1976)). In this case, determining whether a polyeptide fragment of SEQ ID NO:4 binds to a specific antibody, i.e., Mab 3B2, is a simple test that is routinely carried out by those skilled in the art of the invention.

As was discussed above, methods of generating a fragment of a protein defined by SEQ ID NO:4 were well known a the time the invention was filed. Methods of identifying which of those fragments bind to Mab 3B2 are described in the specification, e.g., at page 14, lines 3-16, as well as at page 17, lines 4-12. With a specific antibody in hand (e.g., MAb 3B2, as required by the claim), the teachings in the specification coupled with knowledge in the art fully enable the skilled artisan to identify claimed fragments without undue experimentation. Applicants therefore request withdrawal of the rejection of claim 19.

Written Description

With respect to written description, the Examiner stated:

> Applicant is not in possession of any polypeptide comprising sequence identical to at least 95% of SEQ ID NO:4 in claim 9....Applicant has disclosed only polypeptide of SEQ ID NO:4; therefore, the skilled artisan cannot envision all the contemplated amino acid sequence possibilities recited in the instant claims. Consequently, conception

> cannot be achieved until a representative description of the structural and functional properties of the claimed invention has occurred, regardless of the complexity or simplicity of the method.

Claim 9 has been amended to require the amino acid sequence of SEQ ID NO:4. Therefore, the rejection of claim 9 should be withdrawn.

With respect to claim 18 and 19, Applicants submit that the specification describes the structural and functional properties of a representative number of examples so as to show that Applicants were in possession of the claimed genus. For example, polypeptides of APP-2 (the amino acid sequence of which is defined by SEQ ID NO:4) that bind to Mab 3B2 are located in the portion of the protein that is exposed on the cell surface of activated platelets (see e.g., page 10, lines 18-20, and page 25, lines 27-29, of the specification). Among fragments which bind to Mab 3B2, the specification describes at least three examples: fragments that lack a transmembrane domain of APP-2 (SEQ ID NO:4); fragments that lack an intracellular domain of APP-2; and APP-2 fragments that lack both the transmembrane and intracellular domains (page 7, lines 1-16, of the specification). Thus, in view of the description of at least three species by physical/structural characteristics, Applicants submit that the specification fulfills the requirements of the statute for written description of the genus defined by claim 18 and 19. Withdrawal of this rejection is respectfully requested.

CONCLUSION

On the basis of the foregoing amendments and remarks, Applicant respectfully submits that the pending claims are in condition for allowance. The Commissioner is hereby authorized to charge any required fees, or credit any overpayment, to Deposit Account No. 50-0311 (Reference No. 21509-020 DIV).

Respectfully submitted,

Ingrid A. Beattie, Reg. No. 42,306
Attorney for Applicant
c/o MINTZ LEVIN
One Financial Center
Boston, Massachusetts 02111
Tel.: (617) 542 6000
Fax: (617) 542-2241

APPENDIX:
MARKED-UP VERSION OF AMENDMENTS

In the Specification:

Replace the paragraph beginning on page 1, line 5, with the following paragraph.

This application claims priority from U.S. serial No. 60/005,074 and is a divisional of U.S. Serial No. 0[9]8 /725,758 (now issued as U.S. Patent No. 6,160,108), which was filed on October 4, 1996, originally filed as provisional application.

In the claims:

9. (amended) A substantially pure polypeptide comprising [a] the amino acid sequence [identical to at least 95%] of SEQ ID NO:4.

10. (amended) [The polypeptide of claim 9, said] A polypeptide comprising the amino acid sequence encoded by SEQ ID NO:3.

18. (amended) A polypeptide comprising an antigenic fragment of the polypeptide of claim 9, wherein said fragment is at least 10 residues in length and wherein said fragment lacks a transmembrane domain.

19. (amended) A substantially pure polypeptide [having the] comprising a fragment of a sequence of a naturally-occurring platelet activation polypeptide [that comprises an epitope which], wherein said sequence is SEQ ID NO:4 and wherein said polypeptide binds to MAb 3B2 (ATCC Designation No. CRL-11986).

23. (new) The polypeptide of claim 18, wherein said fragment is at least 20 residues in length.

23. (new) The polypeptide of claim 18, wherein said fragment is at least at least 50 residues in length.

24. (new) The polypeptide of claim 18, wherein said fragment is at least at least 60 residues in length.

25. (new) The polypeptide of claim 18, wherein said fragment is at least at least 100 residues in length.

26. (new) The polypeptide of claim 18, wherein said fragment is at least at least 200 residues in length.

27. (new) The polypeptide of claim 18, wherein said fragment is at least at least 300 residues in length.

9. (new) The polypeptide of claim 19, wherein said fragment is at least 20 residues in length.

29. (new) The polypeptide of claim 19, wherein said fragment is at least at least 50 residues in length.

30. (new) The polypeptide of claim 19, wherein said fragment is at least at least 60 residues in length.

31. (new) The polypeptide of claim 19, wherein said fragment is at least at least 100

residues in length.

32. (new) The polypeptide of claim 19, wherein said fragment is at least at least 200 residues in length.

33. (new) The polypeptide of claim 19, wherein said fragment is at least at least 300 residues in length.